GOVERNMENT OF INDIA
HEALTH AND FAMILY WELFARE
LOK SABHA

UNSTARRED QUESTION NO:4732
ANSWERED ON:18.04.2001
CLEARING OF DRUGS
BALIRAM;P.R. KHUTE

Will the Minister of HEALTH AND FAMILY WELFARE be pleased to state:

(a) whether DG Health is now clearing new drugs without the consent of DCGI;

(b) if so, DG Health has favoured by clearing 2 New drugs within 2 days of M/s Nicholas Piramal Group;

(c) if so, the procedure adopted whether the expert opinion were obtained for new Drugs;

(d) whether DG Health has violated the Drugs and Cosmetics Act in granting the favour; and

(e) if so, the details thereof?

Answer

THE MINISTER OF STATE IN THE MINISTRY OF HEALTH AND FAMILY WELFARE (SHRI A. RAJA)

(a) No, Sir. As per the provisions of the Drugs and Cosmetics Rules the approval for new drugs is given by the Drug Controller of India.

(b) & (c) The application of M/s Nicholas Piramal India was received for import and marketing of 2 drugs on 24.4.2000.After evaluation and recommendations by leading Oncologists in the country, permission was given by the DCG(I) on 10.7.2000.

(d) & (e) Do not arise in view of (b) and (c) above.